

The reagent pipette assembly 470 is preferably an off-the-shelf product. The presently preferred unit is the Cavro Robotic Sample Processor, model RSP9000, with two gantry arms.

The pipette units 480, 482 of the reagent pipette assembly 470 are each preferably coupled to a respective syringe pump (not shown) (the Cavro XP 3000 has been used) and a DC driven diaphragm system fluid wash pump. The syringe pumps of the reagent pipette assembly 470 are preferably mounted to the internal frame structure 62 within the housing 60 of the analyzer 50 at a position above the left-hand side of the chemistry deck 200 and are connected to the respective pipette units 480, 482 by suitable tubing (not shown) or other conduit structures.

Each pipette unit 480, 482 preferably includes capacitive level sensing capability.

Capacitive level sensing, which is generally known in the medical instrumentation arts, employs capacitance changes when the dielectric of a capacitor, formed by the pipette unit as one plate of the capacitor and the structure and hardware surrounding a container engaged by the pipette unit as the opposite plate, changes from air to fluid to sense when the probe of the pipette unit has penetrated fluid within a container. By ascertaining the vertical position of the probe of the pipette unit, which may be known by monitoring the stepper motor which drives vertical movement of the pipette unit, the level of the fluid within the container engaged by the pipette unit may be determined.

Pipette unit 480 transfers reagents from the reagent cooling bay 900 into reaction receptacles disposed within the incubator 606 or the orbital mixer 552, and pipette unit 482 transfers reagent materials from the reagent cooling bay 900 into reaction receptacles disposed within the amplification incubator 604 or the orbital mixer 552.

The pipette units 480, 482 use capacitive level sensing to ascertain fluid level within a container and submerge only a small portion of the end of the probe of the pipette unit to pipette fluid from the container. Pipette units 480, 482 preferably descend as fluid is pipetted into the respective tubular probes 481, 483 to keep the end of the probes submerged to a constant depth. After drawing reagent into the tubular probe of the pipette unit 480 or 482, the pipette units create a minimum travel air gap of 10  $\mu$ l in the end of the respective probe 481 or 483 to ensure no drips from the end of the probe as the pipette unit is moved to another location above the chemistry deck 200.

The results of the assay preferably performed in the analyzer 50 of the present invention are ascertained by the amount of chemiluminescence, or light, emitted from a receptacle vessel 162 at the conclusion of the appropriate preparation steps. Specifically, the results of the assay

are determined from the amount of light emitted by label associated with hybridized polynucleotide probe at the conclusion of the assay. Accordingly, the processing deck 200 includes a luminometer 950 for detecting and/or quantifying the amount of light emitted by the contents of the reaction receptacle. Briefly, the luminometer 950 comprises a housing through 5 which a reaction receptacle travels under the influence of a transport mechanism, a photomultiplier tube, and associated electronics. Various luminometer embodiments will be described in detail below.

The processing deck 200 also preferably includes a deactivation queue 750. The assay performed in the analyzer 50 involves the isolation and amplification of nucleic acids belonging 10 to at least one organism or cell of interest. Therefore, it is desirable to deactivate the contents of the reaction receptacle 160, typically by dispensing a bleach-based reagent into the reaction receptacle 160 at the conclusion of the assay. This deactivation occurs within the deactivation queue 750.

Following deactivation, the deactivated contents of the reaction receptacle 160 are stored 15 in one of the liquid waste containers of the lower chassis 1100 and the used reaction receptacle is discarded into a dedicated solid waste container within the lower chassis 1100. The reaction receptacle is preferably not reused.

#### ANALYZER OPERATION

The operation of the analyzer 50, and the construction, cooperation, and interaction of the 20 stations, components, and modules described above will be explained by describing the operation of the analyzer 50 on a single test specimen in the performance of one type of assay which may be performed with analyzer 50. Other diagnostic assays, which require the use of one or more of the stations, components, and modules described herein, may also be performed 25 with the analyzer 50. The description herein of a particular assay procedure is merely for the purpose of illustrating the operation and interaction of the various stations, components, and modules of the analyzer 50 and is not intended to be limiting. Those skilled in the art of diagnostic testing will appreciate that a variety of chemical and biological assays can be performed in an automated fashion with the analyzer 50 of the present invention.

The analyzer 50 is initially configured for an assay run by loading bulk fluids into the 30 bulk fluid storage bay of the lower chassis 1100 and connecting the bulk fluid containers to the appropriate hoses (not shown).

5 The analyzer is preferably powered up in a sequential process, initially powering the stations, or modules, that will be needed early in the process, and subsequently powering the stations that will not be needed until later in the process. This serves to conserve energy and also avoids large power surges that would accompany full analyzer power-up and which could trip circuit breakers. The analyzer also employs a "sleep" mode during periods of nonuse. During sleep mode, a minimal amount of power is supplied to the analyzer, again to avoid large surges necessary to power-up an analyzer from complete shut-down.

10 A number of reaction receptacles 160, preferably in the form of plastic, integrally formed multiple-tube units (MTUs), which are described in more detail below, are loaded through opening 68 into the input queue 150. Henceforth, the reaction receptacles 160 will be referred to as MTUs, consistent with the preferred manner of using the analyzer 50.

15 The reaction receptacle shuttle assembly (not shown) within the input queue 150 moves the MTUs 160 from the loading opening 68 to the pick-up position at the end of the queue 150. The right-side transport mechanism 500 takes an MTU 160 from the end of the queue 150 and moves to a bar code reader (not shown) to read the unique bar code label on that MTU which identifies that MTU. From the bar code reader, the MTU is moved to an available specimen transfer station 255 below opening 252.

#### MULTIPLE TUBE UNITS

20 As shown in FIGURE 58, an MTU 160 comprises a plurality of individual receptacle vessels 162, preferably five. The receptacle vessels 162, preferably in the form of cylindrical tubes with open top ends and closed bottom ends, are connected to one another by a connecting rib structure 164 which defines a downwardly facing shoulder extending longitudinally along either side of the MTU 160.

25 The MTU 160 is preferably formed from injection molded polypropylene. The most preferred polypropylene is sold by Montell Polyolefins, of Wilmington, Delaware, product number PD701NW. The Montell material is used because it is readily moldable, chemically compatible with the preferred mode of operation of the analyzer 50, and has a limited number of static discharge events which can interfere with accurate detection or quantification of 30 chemiluminescence.

An arcuate shield structure 169 is provided at one end of the MTU 160. An MTU manipulating structure 166 to be engaged by one of the transport mechanisms 500, 502 extends